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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

EXAMINER	
COBANOGLU, DILEK B	
ART UNIT	PAPER NUMBER
3626	
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04/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/997,962	HANSON ET AL.	
	Examiner	Art Unit	
	DILEK B. COBANOGLU	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,19-30 and 37-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,19-30 and 37-43* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/2009 has been entered.

Claim Objections

2. Claim objection has been withdrawn because the Applicant amended claim 16 to correct the typographical error.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 16, 19-30, 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775) in view of Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1).

A. Claim 16 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. providing a single source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19), wherein said single source of a drug includes an individual drug and an individual medical device, (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16),

ii. associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source,

iii. providing data associated with said drug in said single source to be administered from providing of said single source to said disposal of said single source (Walker; abstract, col. 2, lines 7-19, col. 10, lines 56-65),

iv. disposing of said single source (Walker; col. 10, lines 56-65),

v. storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code, and

vi. retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source, administration of said drug from said source, and disposal of said source.

Walker fails to expressly teach "associating a unique tracking code with said single source, wherein said unique tracking code is

unique as to a said single source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "associating a unique tracking code with said single source, wherein said unique tracking code is unique as to a said single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40, col. 5, lines 48-54).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "storing said data in association with said tracking code on a storage device, whereby the stored data may be altered while still being associated with the same unique tracking code" and "retrieving the stored data from said storage device using said tracking code, wherein the stored data tracks the administration of said drug from said source from providing of said source to said disposing of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook teaches these limitations in col. 3, lines 8-24, col. 3, lines 32-40.

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source, administration of said drug from said source, and disposal of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "retrieving the stored data from said storage device using said tracking code, wherein the stored data, retrieved by the tracking code from the storage device, tracks the preparation of said source, administration of said drug from said source, and disposal of said source" (Brook; abstract, col. 3, lines 8-24, col. 3, lines 32-40, col. 5, lines 48-54, col. 6, lines 36-55 and col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as

disclosed by Brook with the motivation of minimizing the manual entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

B. Claims 19-26 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 19-26 are rejected for the same reasons given in the previous Office Action (paper number 7), and incorporated herein.

C. Claim 27 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparation of a single source of a drug to be administered to a patient (Walker; abstract, col. 2, lines 7-19), wherein said single source of a drug includes an individual drug and an individual medical device (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16)

ii. affixing said single source in a cradle (Walker; col. 6, lines 20-37),

iii. providing a label having a bar code corresponding to a unique tracking code affixed to at least one of said source and said cradle (Walker; col. 6, lines 20-37), wherein said unique tracking code is unique as to said single source,

iv. identifying data associated with said drug in said single source and said patient (Walker; col. 1, lines 54-67, col. 2, lines 28-47),

v. storing said data in association with said unique tracking code on a storage device (Walker; col. 5, lines 26-40, col. 13-47),

vi. administering a quantity of said drug to a patient from said single source (Walker; col. 5, lines 26-40, col. 13-47),

vii. disposing of said single source after administration of said drug to a patient (Walker; col. 10, lines 41-65),

viii. updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device, and

ix. retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said drug and said sour from preparation of said source to disposing of said source.

Walker fails to expressly teach "a unique tracking code is unique as to a single source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "a unique tracking code is unique as to a single source" (Brook; abstract, col. 3, lines 15-24, col. 3, lines 32-40).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual

entry of tracking data and automatically update the requisite records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

Walker fails to expressly teach "updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device and retrieving said data from said storage device using said unique tracking code, wherein said data, retrieved by the tracking code from the storage device, tracks said drug and said sour from preparation of said source to disposing of said source". However, this feature is well known in the art, as evidenced by Brook.

In particular, Brook discloses "updating said data and said quantity of said drug administered in association with the same unique tracking code on said storage device" (Brook; abstract, col. 3, lines 8-24, col. 3, lines 32-40, col. 5, lines 48-54, col. 6, lines 36-55 and col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Brook with the motivation of minimize the manual entry of tracking data and automatically update the requisite

records to improve the accuracy, speed and efficiency of the drug tracking (Brook; col. 3, lines 9-14).

D. Claims 28-30 have not been amended, and Applicant does not appear to argue the separate patentability of these claims. As such, claims 28-30 are rejected for the same reasons given in the previous Office Action (paper number 9), and incorporated herein.

E. Claims 38-39 recites the method of claims 16 and 27 wherein said unique tracking code is stored in said storage device in association with the identification of a patient to be administered said drug (Walker; abstract, col. 2, lines 7-19, col. 3, lines 26-30, col. 9, lines 12-15).

F. Newly added claims 41-42 recite the method of claims16 and 27, wherein said unique tracking code conveys no information other than the identity of the tracking code (Walker; col. 2, lines 7-19).

5. Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brook et al. (hereinafter Brook) (U.S. Patent No. 6,170,746 B1) in view of Walker et al. (hereinafter Walker) (U.S. Patent No. 5,651,775).

A. Claim 37 has been amended now to recite a method for tracking data associated with a medical device adapted for the administration of a drug to a patient, said method comprising:

i. preparing a single source of a drug to be administered to a patient (Brook; col. 6, line 56 to col. 7, line 31), wherein said single source of a drug includes an individual drug and an individual medical device,

ii. associating a unique tracking code with said single source (Brook; col. 5, lines 48-54),

iii. providing first data associated with said tracking code relating to said drug in said single source to be administered (Brook; col. 5, lines 48-54),

iv. providing second data representing an amount of said drug in said single source administered to said patient from said single source associated with said tracking code (Brook; col. 7, lines 32-50, col. 8, lines 27-65),

v. providing third data associated with disposing of said single source (Brook; col. 6, lines 36-55, col. 10, line 51 to col. 11, line 12),

vi. storing said first, second and third data in association with said tracking code on a storage device (Brook; col. 6, lines 2-19),

vii. retrieving said first, second and third data from said storage device using said tracking code, whereby said first, second and third data associated with said tracking code, and retrieved by the tracking code from the storage device, tracks said single source from said preparing of said source through administration of said drug to a patient to said disposal thereof (Brook; col. 5, lines 18-35, col. 6, lines 2-19, col. 8, lines 27-65, col. 9, lines 40-53).

Brook fails to expressly teach "single source of a drug includes an individual drug and an individual medical device". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "single source of a drug includes an individual drug and an individual medical device" (Walker; abstract, col. 2, lines 28-34, col. 3, lines 35-41, col. 3, lines 8-16).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of returning the unused drugs and therefore reducing of drug waste (Walker; col. 3, lines 9-14).

B. Claim 40 recites the method of claim 37 wherein said unique tracking code is stored in said storage device in association with the identification of a patient to be administered said drug (Walker; abstract, col. 2, lines 7-19, col. 3, lines 26-30, col. 9, lines 12-15).

Brook fails to expressly teach "said unique tracking code is stored in said storage device in association with the identification of a patient to be administered said drug". However, this feature is well known in the art, as evidenced by Walker.

In particular, Walker discloses "said unique tracking code is stored in said storage device in association with the identification of a

patient to be administered said drug" (Walker; abstract, col. 2, lines 7-19, col. 3, lines 26-30, col. 9, lines 12-15).

It would have been obvious to one having ordinary skill in the art at the time of the invention to include the aforementioned limitation as disclosed by Walker with the motivation of real time monitoring of patient delivered drugs (Walker; abstract).

C. Newly added claim 43 recites the method of claim 37, wherein said unique tracking code conveys no information other than the identity of the tracking code (Brook; col. 4, lines 11-24, , col. 5, lines 48-63).

Response to Arguments

6. Applicant's arguments filed 02/04/2009 have been fully considered but they are not persuasive. Applicant's arguments will be addressed below in the order in which they appear.

A. In response to Applicant's argument about "Brook does not disclose a unique tracking code"; Examiner respectfully submits that Brook teaches a barcode identifying the drug" as explained in the previous office actions.

B. In response to Applicant's argument about "Brook does not disclose a unique tracking code which is associated with a single source of a drug"; Examiner respectfully submits that Brook teaches "…the portable scanning and printing system automatically prompts the user to pick drugs identified by pick-list information received from the host system. After prompting the user to pick a particular drug, by displaying information identifying the drug to be picked for a

particular destination, the user scans a barcode associated with the identified drug, the barcode typically being located on the shelf supporting the drug, or on a drug container. Upon receiving a scanned barcode representing the identity of a drug, the portable scanning and printing system compares the identity of the drug represented by the scanned barcode data to the identity of the drug received from the host system." In col. 4, lines 11-24. Therefore Brook teaches a barcode associated with a single drug and a single source.

C. In response to Applicant's argument about "Brook does not disclose a tracking code which can retrieve "first, second and third data" from the storage device"; Examiner respectfully submits that Brook teaches "the portable scanning and printing system includes a memory for collecting data, a display, a printer and a number of input means including a barcode scanner, a keyboard or keypad, and a wireless communication interface. The wireless communication interface allows the portable scanning and printing system to communicate with a host system having a memory for storing drug tracking records wherein the host system automatically updates the drug tracking records from information transmitted thereto by the portable scanning and printing system." In col. 3, lines 15-24. and "A radio frequency access point 19 on the local area network allows the P.C. based server 10 to communicate i.e. transmit and receive, wireless communications with the portable barcode scanning and printing system 20." In col. 5, lines 25-30.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to DILEK B. COBANOGLU whose telephone number is (571)272-8295. The examiner can normally be reached on 8-4:30.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher L. Gilligan can be reached on 571-272-6770. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

9. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/D. B. C./
Examiner, Art Unit 3626
4/26/2009

/C. Luke Gilligan/
Supervisory Patent Examiner, Art Unit 3626